

### REMARKS

It is respectfully requested that this application be reconsidered in view of the above amendments and the following remarks and that all of the claims remaining be allowed.

#### Claim Amendments

Claims 22-24 have been amended to delete the reference to "IL-B50" in the preambles. Since the recitation "IL-B50" in the preamble does not limit the scope of each of the claims, which is fully delineated by the claim body in each case, no new matter has been added by these amendments. The Examiner is hereby requested to enter these amendments.

Applicants submit that all claim amendments presented herein or previously are made solely in the interest of expediting allowance of the claims and should not be interpreted as acquiescence to any rejections or ground of unpatentability. Applicants reserve the right to file at least one continuing application to pursue any subject matter that is canceled or removed from prosecution due to the amendments.

#### Election/Restriction and Claim Numbering (Paragraphs 1-4 of the Office Action)

The Office Action state that claims 21-24 and 26-32 were added in the paper filed September 19, 2003 (hereinafter "the reply filed September 19"), and these claims have been renumbered 21-31. Applicants submit that claims 21-32 were added in the reply filed September 19, and no renumbering was necessary. An entire copy of the reply filed September 19 is enclosed herewith for the convenience of the Examiner. Claims 21-32, including the allegedly missing claim 25, are listed under both "Claim List" and "Appendix A" in the reply filed September 19. Specifically, claim 25 can be found on page 3 and page 11.

The Office Action further states that the renumbered claims 21-24 and 30-31 have been constructively elected, and claims 25-29 have been withdrawn. Since claim 25, as added in the reply filed September 19, is also directed to the elected invention, Applicants submit that claims 21-25 and 31-32 (original numbers) should be examined, and claims 26-30 (original numbers) should be withdrawn.

Applicants wish to thank the Examiner for reminding Applicants of the procedure of rejoinder.

Specification (Paragraph 5 of the Office Action)

The Office Action notes the use of a trademark at page 62, line 20, and advises that trademarks should be capitalized and accompanied by the generic terminology. The trademark appears in the following context:

Remaining cells were stained with a variety of mouse anti-human FITC-conjugated monoclonal antibodies (mAb) including anti-HLA-DR (Becton Dickinson), anti-CD40, anti-CD80 and CD86 (all from Pharmingen) or an Ig-G1 isotype control (Becton Dickinson), and were analyzed with a FACScan® flow cytometer (Becton Dickinson). The trademark, FACScan®, is capitalized and accompanied by the generic terminology (flow cytometer). Therefore, Applicants submit that the use of the trademark is proper.

Rejection Under 35 U.S.C. §112, First Paragraph (Paragraph 6 of the Office Action)

The rejection of claims 22-24 and 31-32 (previously renumbered as claims 30-31) under 35 U.S.C. §112, first paragraph, as allegedly containing subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention, is respectfully traversed for the reasons set forth below.

Claim 22 is directed to a purified polypeptide wherein the polypeptide comprises SEQ ID NO: 4, or a fragment thereof, capable of binding IL-B50 receptors. Claims 23 and 24 are directed to purified polypeptides comprising an amino acid sequence that is at least about 80% identical to the amino acid sequence of SEQ ID NO: 2 and amino acid residues 1-131 of SEQ ID NO:4, respectively, or a fragment thereof, wherein the polypeptide is capable of binding IL-B50 receptors. Claims 31-32 depend from claims 22-24. The Office Action states that the present application provides SEQ ID NO:2 and SEQ ID NO:4, but allegedly does not provide all proteins that share an 80% identity to SEQ ID NO:2 or amino acid residues 1-131 of SEQ ID NO:4, that are capable of binding IL-B50 receptors.

Pursuant to the Guidelines for Examination of Patent Applications Under the 35 U.S.C. 112, Paragraph 1, "Written Description" Requirement, Federal Register 66(4):1099 (2001), possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. *Id.* at 1104.

The present specification describes distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. As the Office Action recognizes, the specification provides the IL-B50 sequences SEQ ID NO:2 and SEQ ID NO:4. The specification further discloses that IL-B50 encompasses a protein having SEQ ID NO:2 or SEQ ID NO:4, significant fragments thereof (page 12, lines 25-28), or proteins or peptides having substantial amino acid sequence identity with the amino acid sequence of the IL-B50 antigen (page 15, lines 7-9). Identity measures will be at least about 35%, generally at least about 40%, often at least about 50%, typically at least about 60%, usually at least about 70%, preferably at least about 80%, and more preferably at least about 90% (page 15, line 29 to page 16, line 2).

The specification also teaches sufficient distinguishing identifying characteristics of the IL-B50 sequences. It is disclosed that the IL-B50 sequence has a signal peptide at the N-terminus, which is about 33 residues long (page 10, lines 23-25). IL-B50 exhibits structural motifs characteristic of a member of the short chain cytokines, such as IL-7 (page 10, lines 26-29). Short chain cytokines are known to have four alpha helices (see, e.g., pages 742-744 of Fundamental Immunology (4<sup>th</sup> ed.) by Paul, Lippincott-Raven, Philadelphia-New York; copy enclosed herewith). A sequence alignment of IL-7 and IL-B50, showing four helices, is provided in Figures 1A and 1B. It is further disclosed that helices A and D are most important in receptor interaction (page 40, lines 21-22). Surface exposed residues would affect receptor binding (page 40, lines 25-26). Sequence variants preferably have substitutions away from the conserved cysteines, and often will be in the regions away from the helical structural domains

(page 17, lines 7-10). Based on these disclosures, a person of ordinary skill would have agreed that Applicants were in possession of the IL-B50 variants that are encompassed by the rejected claims.

Accordingly, the specification describes sufficient distinguishing identifying characteristics of the claimed invention. Therefore, the written description requirement is satisfied, and withdrawal of this rejection is respectfully requested.

Rejection Under 35 U.S.C. §112, Second Paragraph (Paragraphs 7-9 of the Office Action)

The rejection of claims 21-24 and 31-32 (previously renumbered as claims 30-31) under 35 U.S.C. §112, second paragraph, as allegedly being indefinite, is respectfully traversed for the reasons set forth below.

The Office Action states that the term "IL-B50 polypeptide" in claims 21-24 is allegedly indefinite as a limitation. Applicants disagree since the metes and bounds of the claimed polypeptides are clearly delineated by the body of each of the claims, while the preamble term "IL-B50 polypeptide" does not further limit the scope of the claims. Nevertheless, in the interest of expediting prosecution, "IL-B50" has been deleted from the preamble of claims 22-24 (claim 21 does not recite this claim). Therefore, this rejection is now moot, and its withdrawal is respectfully requested.

Rejection Under 35 U.S.C. §102 (Paragraphs 10-11 of the Office Action)

The rejection of claims 21-24 and 31-32 (previously renumbered as claim 30-31) under 35 U.S.C. §102 in view of Sims et al. (US Patent No. 6,555,520, filed May 9, 2001; hereinafter "the Sims patent") is respectfully traversed for the reasons set forth below.

The Office Action contends that the utility of the claimed IL-B50 sequence is fully disclosed only in the present application, thus taking the position that the effective filing date is established as the filing date of the instant application, namely September 9, 2001. Based on this filing date, the Office Action cites the Sims patent, filed May 9, 2001, as prior art.

It is not required that the utility of a claimed composition to be fully disclosed in a patent application. Pursuant to the Utility Examination Guidelines, Federal Register 66(4), 1092, 1094 (2001): "The patentee is required to disclose only one utility, that is, teach others how to use the invention in at least one way. The patentee is not required to disclose all possible uses". The requirement for utility is that a specific, substantial and credible utility is disclosed for the claimed invention. Federal Register 66(4), at 1098. Credibility of an asserted specific and substantial utility can be assessed from the perspective of one of ordinary skill in the art in view of the disclosure and any other evidence of record (e.g., test data, affidavits or declarations from experts in the art, patents or printed publications) that is probative of the applicant's assertions. Id.

At least one specific, substantial and credible utility has been disclosed in the priority applications for the instant application. For example, U.S. Application No. 60/101,318 (hereinafter "the '318 application"), filed September 21, 1998, discloses that IL-B50 has stimulatory or inhibitory effects on hematopoietic cells, including, e.g., lymphoid cells, such as T-cells, B-cells, natural killer (NK) cells, macrophages, dendritic cells, and hematopoietic progenitors (page 9, lines 9-13 of the '318 application). The '318 application further discloses that IL-B50 is a short chain cytokine exhibiting sequence similarity to IL-7 (page 12, lines 1-4), that IL-B50 and IL-7 are likely to share similar biological functions (page 12, second paragraph, particularly line 32), and that IL-7 exhibits strong effects on lymphopoietic development and differentiation (page 59, lines 21-22). IL-B50 can be used to isolate its receptor (page 49, lines 5-6 of the '318 application), and it was predicted that IL-B50 would bind to the alpha subunit of the IL-7 receptor along with another subunit (page 49, lines 25-28 of the '318 application). Therefore, a skilled artisan would have understood from the '318 application that IL-B50 has similar functions as IL-7, particularly as a stimulating factor for lymphopoietic development and differentiation. In fact, IL-B50 and IL-7 are so closely related that their receptors would share a common subunit.

These functions are further supported by the data disclosed in the present application. For example, it is shown that IL-B50 induces phosphorylation of Stat3 and Stat5 (page 64,

lines 13-16), as well as enhances maturation of dendritic cells (page 67) and expansion/development of T cells (page 68). The IL-B50 receptor has been identified, and it indeed contains the alpha subunit of the IL-7 receptor (pages 63-64). The data thus indicate that IL-B50 is a hematopoietic cytokine most closely related to IL-7 (page 68, lines 25-26 of the present application) which stimulates lymphopoietic development and differentiation. Thus, the utilities asserted in the '318 application are specific, substantial and credible.

Accordingly, the claimed invention is entitled to the benefit of the filing date of the '318 application, namely September 21, 1998. Since the Sims patent was filed on May 9, 2001, with an earliest possible priority date of November 13, 1998, it is not prior art with respect to the claimed invention. Therefore, withdrawal of this rejection is respectfully requested.

#### Conclusions

For the reasons set forth above, Applicants submit that the claims of this application are patentable. Reconsideration and withdrawal of the Examiner's objections and rejections are hereby requested. Allowance of the claims remaining in this application is earnestly solicited.

In the event that a telephone conversation could expedite the prosecution of this application, the Examiner is requested to call the undersigned at (650) 839-5044.

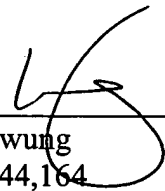
Applicant : Bazan, et al.  
Serial No. : 09/963,347  
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Page : 10 of 10

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Please apply any charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: Mar. 8, 2004

  
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